

Appl. No. 09/993,290 Amdt. dated Reply to Office action of July 29, 2005

REMARKS/ARGUMENTS

In response to the Office Action of July 29, 2005, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C.

Claim Status/Support for Amendments

Claims 1, 39, 40 and 44 have been amended. Claims 2-38 were cancelled in a previous response (filed on December 10, 2004). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from consideration on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer markers of claim 1 (the examined claim of the elected Group I invention).

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendments to the claims made herein.

Claims 1, 39 and 44 were amended to recite the proper

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alternative expression and transition phrases to clearly indicate the intended scope of the claims.

Claim 40 was amended to provide proper antecedent basis for the term "sample" as recited in parent claim 39.

Claims 39 and 44 were amended to delete the term "isolated".

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3 a search of these claims would encompass these specific sequences. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer markers of SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3 are found to be novel, methods and kits limited to their use should also be found novel.

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Interview with the Examiner

Applicants thank the Examiner for courtesies extended during her telephone interview with Applicants' representatives, Ferris Lander and Katharine Davis, on September 15, 2005.

The use of Markush language (alternative expression) and transitional phrases to delineate the scope of the claims was discussed. Both the Examiner and Applicants' representatives agreed that the amendments to the claims as presented herein are sufficient to overcome the rejection under 35 USC 112, second paragraph.

Rejection under 35 USC 112, second paragraph

Claim 1, as presented on May 11, 2005, stands rejected under 35 USC 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that claim 1 does not include a proper transition phrase "comprising" or "consisting of" in the claim. The claim is in the proper Markush Format reciting-selected from the group consisting of. However, while this language provides closed interpretation between SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3, it does not clearly identify Applicants' intended scope for SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3.

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The "alternative expression" language of claim 1 has been amended herein, the Markush format has been replaced by "or" terminology (see MPEP 2173.05 (h) I, II). Claim 1 has also been amended to include the transition phrase "consisting of". The phrase "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03). Since claim 1 now recites an isolated biopolymer marker consisting of SEQ ID NO:1; consisting of SEQ ID NO:2 or consisting of SEQ ID NO:3, the scope is clearly delineated as limited to these specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) as disclosed in the instant specification as originally filed at page 46, thus excluding any additional amino acid residues or other elements.

Accordingly, Applicants have now clarified the metes and bounds of the claims and respectfully request that the above-rejection under 35 USC 112, second paragraph be withdrawn.

Rejections under 35 USC 102

Claim 1, as presented on May 11, 2005, stands rejected under 35 USC 102(b) as allegedly being anticipated by Harrison et al. (US Patent 5,849,297).

The Examiner states that Harrison et al. discloses sequences comprising or having SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. See GenCore protein search dated 8/5/04. Although the reference is

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silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers. Applicants SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 are disclosed as sequence identification number 1 in the reference to Harrison. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Harrison et al. encompasses the entire amino acid sequence of the complement C3 protein. The claimed biopolymer markers SEQ ID NOS:1-3 are fragments of this entire amino acid sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these three specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) thus excluding the disclosure of Harrison et al. No where does Harrison et al. specifically teach the claimed biopolymer marker sequences (SEQ ID NOS:1-3). Nor does Harrison et al. teach any peptide which is indicative of a link to insulin resistance.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Harrison et al. and respectfully request that this rejection under

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35 USC 102(b) be withdrawn.

Claim 1, as presented on May 11, 2005, stands rejected under 35 USC 102(a) as allegedly being anticipated by Harrison et al. (US Patent 6,221,657 B1).

The Examiner states that Harrison et al. discloses sequences comprising or having SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. See GenCore protein search dated 8/5/04. Although the reference is silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers. Applicants SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 are disclosed as sequence identification number 1 in the reference to Harrison. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Harrison et al. encompasses the entire amino acid sequence of the complement C3 protein. The claimed biopolymer markers SEQ ID NOS:1-3 are fragments of this entire amino acid sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these three

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specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) thus excluding the disclosure of Harrison et al. No where does Harrison et al. specifically teach the claimed biopolymer marker sequences (SEQ ID NOS:1-3). Nor does Harrison et al. teach any peptide which is indicative of a link to insulin resistance.

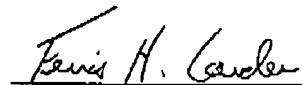
Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Harrison et al. and respectfully request that this rejection under 35 USC 102(a) be withdrawn.

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CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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